DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

5/916d

October 15, 2001

WARNING LETTER
CHI-5-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John C. Chang, President
Burnham Laboratories, Inc.
7117 N. Austin Ave
Niles, IL 60714-4617

Dear Mr. Chang:

An inspection of your firm was conducted from August 21 through 30, 2001, by Investigator Bruce McCullough. The inspection revealed significant deviations from Title 21, Code of Federal Regulations (21 CFR), Parts 210 and 211. These deviations cause the pharmaceutical products manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include, but are not limited to the following:

1. Failure to conduct at least one test to verify the identity of each component of a drug product [21 CFR 211.84(d)(1)]. The inspection revealed that your firm has not established specifications for any component used to manufacture pharmaceuticals.

2. Failure to test each component for conformity with all appropriate written specifications for purity, strength, and quality, or to establish the reliability of the supplier's analyses in order to accept their reports of analysis [21 CFR 211.84(d)(2)].

3. Failure to establish and utilize adequate equipment cleaning procedures and related test methods [21 CFR 211.67(b)]. The inspection disclosed that your firm has not conducted any cleaning validation studies for the cleaning of the formulation tanks, kettles, pumps, and pipes and for the filling equipment.

4. Failure to maintain equipment cleaning and use logs covering the maintenance, cleaning, sanitizing and inspection of equipment used in the production of pharmaceutical products [21 CFR 211.182]. The inspection revealed that your firm's SOP #2.02 entitled "Cleaning & Maintenance log book" requires that these activities be recorded also.

5. Failure to validate manufacturing processes used in the production of pharmaceutical products [21 CFR 211.100(a)]. The inspection revealed that your firm has not conducted process validation studies for several of the pharmaceutical products you manufacture such as "Ultra Skin Care with Sunscreen."

6. Failure to conduct validation studies of your firm's Purified Water system that produces water for compounding in order to assure that objectionable microorganisms are not present [21 CFR 211.113(a)].

The above list of violations, as well as the Form FDA 483, Inspectional Observations, that was issued to you at the conclusion of the inspection, is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm is in compliance with the requirements of the Act and all applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to the attention of George F. Bailey, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director